

**● PRINTER RUSH ●**  
**(PTO ASSISTANCE)**

Application :	10/607719	Examiner :	Tran
From:	<i>NMB</i>	Location:	<input checked="" type="radio"/> IDC <input type="radio"/> FMF <input type="radio"/> FDC
		GAU :	
		Date: 1-12-06	

Tracking #: *10/607719* Week Date: *11-28-05*

DOC CODE	DOC DATE	MISCELLANEOUS
<input type="checkbox"/> 1449		<input type="checkbox"/> Continuing Data
<input type="checkbox"/> IDS		<input type="checkbox"/> Foreign Priority
<input type="checkbox"/> CLM		<input type="checkbox"/> Document Legibility
<input type="checkbox"/> IIFW		<input type="checkbox"/> Fees
<input type="checkbox"/> SRFW		<input checked="" type="checkbox"/> Other <i>Bib. Sheet</i>
<input type="checkbox"/> DRW		
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<input type="checkbox"/> SPEC	6-27-2003	

[RUSH] MESSAGE:	<i>There are two lines of continuing data on the bib data sheet but none present in the specification.</i>
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<i>Thank you, NMB</i>	

[XRUSH] RESPONSE:	<i>1 done</i>
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<b>INITIALS:</b> <i>[Signature]</i>	

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REV 10/04

# **Self-emulsifying Formulations of Fenofibrate and/or Fenofibrate Derivatives with Improved Oral**

## **Bioavailability and/or Reduced Food Effect**

*(b)(4)*  
This application is a continuation-in-part of 10324953 filed Dec. 20, 2002 which claims benefit of 60/392791 filed June 28, 2002.

### **5 FIELD OF THE INVENTION**

The present invention relates to a non-aqueous self-emulsifying oral pharmaceutical formulations of fenofibrate or fenofibrate derivatives having an improved oral bioavailability and/or reduced food effect when compared to a commercial available formulation.

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### **BACKGROUND OF THE INVENTION**

Fenofibrate is a fibrate used in the treatment of endogenous hyperlipidaemias, hypercholesterolaemias and hypertriglyceridaemias in adults. The preparation of 15 fenofibrate is disclosed in US patent. No. 4,058,552. Fenofibric acid, the active metabolite of fenofibrate, produces reductions in total cholesterol, LDL cholesterol, apolipoprotein B, total triglycerides and triglyceride rich lipoprotein (VLDL) in treated patients. Also, treatment with fenofibrate results in increases in high-density lipoprotein (HDL) and apoproteins apoAI and apoAII. Prolonged treatment with fenofibrate at the 20 rate of 300 to 400 mg per day makes it possible to obtain a reduction in total cholesterol of 20 to 25% and a reduction in the levels of triglycerides of 40 to 50%. It thus opposes the development of arteriosclerosis. The customary adult fenofibrate dosage is three gelatin capsules per day, each containing 100 mg of fenofibrate. It is known that fenofibrate absorption variations are observed depending on whether the drug was 25 ingested with a high or low fat meal (Atkins J.C. and D. Faulds (1997) Drugs 54(4) 615 – 633).